



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Medica Corp.
c/o Dr. Photios Makris
Director of Regulatory Affairs/Quality Assurance
5 Oak Park Drive
Bedford, MA 01730

JUL 17 2009

Re: k090734
Trade Name: EasyRA Direct Low Density Lipoproteins Cholesterol Reagent
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, subject to 862.9(c)(4)
Product Codes: MRR, JIX, JJY
Dated: July 01, 2009
Received: July 02, 2009

Dear Dr. Makris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

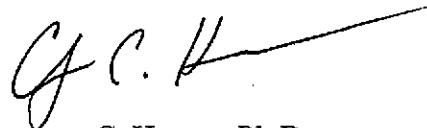
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C.C. Harper', with a long horizontal line extending to the right.

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090734

Device Name: EasyRA direct Low Density Lipoproteins (dLDL) cholesterol Reagent

Indications For Use: The EasyRA dLDL reagent is intended for the quantitative determination of Low Density Lipoproteins in human serum, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. The LDL Cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Device Name: EasyRA direct Low Density Lipoproteins (dLDL) cholesterol Calibrator

Indications For Use: The EasyRA dLDL calibrator facilitates measurements of LDL Cholesterol on the EasyRA clinical chemistry analyzer when used in conjunction with Medica's dLDL reagent. The dLDL calibrator is used to establish a point of reference that is used in the determination of values in the measurement of LDL Cholesterol in human serum.

Device Name: EasyRA EasyQC Quality Control material

Indications For Use: The EasyRA EasyQC material validates measurements of LDL Cholesterol on the EasyRA clinical chemistry analyzer when used in conjunction with Medica's dLDL reagent and calibrator. The EasyQC is used to estimate test precision and to detect systemic analytical deviations that may arise from reagent or analytical instrument variation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K090734